REMARKS

The Examiner has imposed a restriction requirement, and requested that Applicants elect one of two identified groups of claims for prosecution in connection with the present application. The groups of claims are as follows:

Group I Claims 57-103, drawn to a device, a kit and a biodegradable sheet for preparing a device; and

Group II Claims 104-112, drawn to a method of using a plurality of biodegradable guiding units for promoting regeneration of an injured nerve.

APPLICANTS' ELECTION

Applicants respectfully elect Group I, Claims 57-103, with traverse. Applicants reserve the right to file a divisional application for the non-elected claims during the pendency of this application. Additionally, Applicants elect Species C, stem cells or precursor cells of claims 76 and 99, with traverse, in response to the species election requirement.

Arguments in Support of Traversal

The Examiner has applied the Unity of Invention standards under PCT Rule 13.1 and 13.2. According to the Examiner, the groups of claims do not relate to a single general inventive concept because they lack the same or corresponding "*special technical feature.*" This is because, according to the Examiner, the invention of claim 57 is allegedly known in the art as demonstrated by U.S. Patent 6,548,569.

Applicant recognizes that whether or not any particular technical feature makes a contribution over the prior art, and therefore constitutes a "*special technical feature*" may be considered with respect to novelty and inventive step. That is, the Examiner may consider the prior art in making his Unity of Invention determination. In this case, however, the Examiner has not provided sufficient comments as to how U.S. Patent 6,548,569 teaches or suggests each and every feature of the invention defined by the claims of Groups I and II, including Species A-C. As a result, the basis for the Restriction Requirement is incomplete. If the Examiner maintains the Restriction Requirement, then he should at least point out (by column and line) how the asserted reference meets each and every feature of the invention defined by the claims of Groups I and II, including Species A-C. Furthermore, Applicant respectfully submits that independent claim 104 (of Group II) contains similar technical features to those set forth in independent claim 57 (of Group I).

Even though the Examiner has not pointed out exactly how the '569 Patent meets every feature of the invention as defined by the claims of Groups I and II, Applicants submit that the inventions defined by claims 57-103 do indeed have special technical features which define a contribution over the '569 Patent (See page 6, lines 26-31 and page 7, line 18 to page 8, line 30 of the present application).

U.S. Patent No. 6,485,569 discloses devices formed of or including a biodegradable polyhydroxy alkanoate polymer having controlled degradation rates of less than one year *in vivo*, wherein the degradation rate is manipulated through the chemical or physical composition of the polymer. U.S. Patent No. 6,485,569 does not relate the *in vivo* degradation time of the devices to the tissue regeneration time or the time required for establishing regenerated contact between ends of an injured nerve. Neither does U.S. Patent No. 6,485,569 disclose a device comprising at least two structural elements (such as a nerve encasement structure and a guiding unit) having different *in vivo* degradation times.

In the present invention, the relationship of the degradation time(s) of the biodegradable guiding units (and, for claims 60, 83 and 102, of the biodegradable sheet) to the time required for regenerated contact of nerve ends (or the entire nerve regeneration time) is responsible for the improved nerve regeneration process. The nerve regeneration process is improved with respect to regeneration time and/or function of the restored nerve.

In particular, the device, the kit and the biodegradable sheet, respectively, aim at increasing the axon density growth rate and/or the quantity of regenerated axons. By using a plurality of biodegradable guiding units, the majority of which are essentially disintegrated at a point in time

when contact between the ends of an injured nerve has been re-established using said device (claims 57, 81 and 100), axon growth is enhanced.

The guiding units may initially act as orientation aids for growing axon sprouts until the regeneration process has established contact between the ends of the injured nerve. Thereafter the regenerated axons formed from the axon sprouts act as natural orientation aids for the succeeding growing axons. The presence of guiding units may restrict or even block the growth of succeeding growing axons, and hence impair the amount of regenerated axons. When the guiding units are essentially disintegrated, they will no longer provide any substantial axon growth blocking effect, thus allowing a larger quantity of regenerated axons to be achieved through an increase in axon density growth.

Alternatively, as set out in claims 60, 83 and 102, at least a majority of the guiding units are essentially disintegrated before the nerve has completely regenerated, and the nerve encasement structure is not essentially disintegrated until the nerve has completely regenerated. Even if a majority of the plurality of guiding units are not degraded at the point in time when regenerated contact of the ends of an injured nerve has been established, an advantageous effect on axon growth is still obtained, due to the fact that the reduction in the axon growth blocking effect allows for an increase in axon

growth while the nerve encasement structure still provides protection for the regenerating axons.

In conclusion, Applicants believe that the claims of Groups I and II do indeed share a single general inventive concept according to Rule 13.1 and that the method claims 104-112 thus should be considered for rejoinder.

Upon the allowance of a claim with a "*special technical feature*" and/or allowance of a generic claim, Applicant respectfully requests rejoinder of all claims containing that "*special technical feature*" and/or all claims dependent on that generic claim.

For all of the above stated reasons, reconsideration and withdrawal of the outstanding restriction/election requirement and favorable allowance of all claims in the instant application are earnestly solicited.

CONCLUSION

Applicants respectfully request that this application be examined on the merits at the earliest possible time.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2548 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By_____

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